

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
Civil Action No. 4:10-CV-35-FL

TRACEY COBB)
)
Plaintiff,)
)
v.)
)
ABBOTT LABORATORIES; ABBOTT)
LABORATORIES, INC.; and ABBOTT)
LABORATORIES, INC., d/b/a Abbot)
Sales, Marketing & Distribution Co.)
)
Defendants.)

**STIPULATED CONSENT PROTECTIVE ORDER
REGARDING THE CONFIDENTIALITY OF DOCUMENTS AND MATERIALS**

THIS CAUSE came to be heard on the joint application of Plaintiff and Defendants, and it appearing to the Court that the discovery and trial in this action may involve the production, disclosure, and filing with the Court of confidential, sensitive or proprietary business information, or trade secrets (collectively referred to as "Confidential Information") requiring protection against unrestricted disclosure or use, including, but not limited to, confidential financial data, marketing or sales planning information, information on pricing and profitability, customer or client lists, trade secrets, product design information, engineering or business plans or strategies, proprietary technical or scientific information, and other proprietary and nonpublic commercial information or commercially and/or competitively sensitive information of the type normally protected from disclosure to the public. This Protective Order governs the production or disclosure of all Confidential Information produced by the parties or their agents during the course of discovery, hearings, or trial in this action. In addition, the parties contemplate that

Confidential Information may be produced by a non-party, and the use of such information in this case is similarly governed by this Order.

THEREFORE, IT IS HEREBY STIPULATED, AGREED AND ORDERED that pursuant to FED.R.CIV.P. 26(c), the following confidentiality provisions shall govern the disclosure, use, dissemination, and filing with the Court of all information, documents or materials designated as "Confidential." Unless modified pursuant to the terms contained in this Protective Order, this Protective Order shall remain in effect.

1. This Protective Order shall govern all documents, the information contained therein, and all other information produced or disclosed during this action, whether revealed in a document, deposition, other testimony, discovery response, or otherwise, by a party in this action (the "Supplying Party") to any other party (the "Receiving Party"), when the same is designated in accordance with the procedures set forth herein.

2. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Supplying Party for purposes of this Protective Order.

3. "Confidential Information" as used herein means any information that is designated pursuant to this Protective Order as "CONFIDENTIAL" by the Supplying Party, whether it is a document, information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response, or information otherwise revealed. In designating material as "CONFIDENTIAL," the Supplying Party will make such designation only as to that material that it believes in good faith constitutes, reflects, discloses, or contains a trade secret or other confidential research, development, or commercial information. The parties, in designating information "Confidential" because it contains a trade

secret, shall designate only information that meets one of the following accepted three definitions of trade secret:

- a. The definition adopted by the United States Food and Drug Administration (“FDA”), 21 C.F.R. § 20.61:

A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

- b. The definition contained in N.C. Gen. Stat. § 66-152(3):

"Trade secret" means business or technical information, including but not limited to a formula, pattern, program, device, compilation of information, method, technique, or process that:

- a. Derives independent actual or potential commercial value from not being generally known or readily ascertainable through independent development or reverse engineering by persons who can obtain economic value from its disclosure or use; and

- b. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

The existence of a trade secret shall not be negated merely because the information comprising the trade secret has also been developed, used, or owned independently by more than one person, or licensed to other persons.

or

- c. The definition contained in the Restatement (Third) of Unfair Competition, § 39 (1995):

A trade secret is any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others.

When the parties designate information “Confidential” because it includes “Confidential

research, development, or commercial information,” the parties shall include information that falls in one of the following categories:

- a. Information protected from disclosure by FDA regulations including, but not limited to, 21 C.F.R. § 20.63.
- b. Information provided to the Supplying Party by third parties with the expectation that the Supplying Party would keep such information confidential, or pursuant to contracts that expressly require the Supplying Party to maintain the confidentiality of the information, or that is otherwise protected from disclosure by statute. 3 Roger M. Milgrim, *Milgrim on Trade Secrets* § 14.02[4][g][ii][A].
- c. Names and other identifying information of patients in clinical studies or adverse event reports as well as the physicians who reported to the Supplying Party adverse events concerning one of their patients. 21 C.F.R. § 20.63(f).
- d. Confidential client, customer, or vendor lists.
- e. Information that is not generally available to the public that relates to, reflects, or was or is used to help form the Supplying Party’s research, business, and legal strategies, processes, or techniques.
- f. Information that is not generally available to the public that relates to consumer purchasing habits, pricing information, sales techniques, sales volumes, or marketing, promotional, business, or research plans that has been compiled by or for the benefit of the Supplying Party.
- g. Information concerning communications with government agencies or regulatory bodies that the relevant governing agency or body deems Confidential by statutes or codified regulation or rule.

4. A party in this action may designate as “CONFIDENTIAL” any document or information produced by or testimony given by any other person or entity that the party reasonably believes discloses protected personal medical, employment, educational, or insurance information, or otherwise qualifies as “Confidential Information” pursuant to this Protective Order.

5. Specific documents and interrogatory responses produced by a Supplying Party shall, if appropriate, be designated as “CONFIDENTIAL” by marking the first page of the document and each subsequent page thereof containing Confidential Information and any answer as follows: “CONFIDENTIAL.”

6. In the event that the Court permits any material produced or provided in this action to be inspected prior to copying and delivery of any copies thereof, the material so inspected is to be treated by the Receiving Party as Confidential Information pending the copying and delivery of any copies of the same by the Supplying Party to the Receiving Party.

7. Precautions will be taken not to improperly disseminate Confidential Information if any documents containing Confidential Information are scanned or copied into a computer or any other device, copied onto a disk, or otherwise transferred to an electronic or computer media. In addition, the electronic/computer media will not be forwarded, copied, or otherwise sent to another unless the electronic/computer media are accompanied with a written statement that the materials contained or enclosed include Confidential Information covered by this Protective Order. The parties expressly agree that no Confidential Information shall be transmitted via email or other electronic means; however, this provision shall not prevent attorneys that represent parties in this action (and the attorneys’ staff members) from transmitting Confidential Information to other attorneys who represent parties in this action (and their staff members) by e-

mail or any other means.

8. Information disclosed at a deposition taken in connection with this action may be designated as "CONFIDENTIAL" by:

a. designating testimony as "CONFIDENTIAL" on the record during the taking of the deposition; or

b. notifying all other parties in writing, within thirty (30) calendar days of receipt of the transcript of a deposition, whereupon each party shall attach a copy of such written designation to the face of the transcript and each copy thereof in that party's possession, custody, or control.

In the event testimony is designated as "CONFIDENTIAL" on the record pursuant to subparagraph (a) above, the stenographic employee or court reporter recording or transcribing such testimony will be directed to bind any transcript page(s) containing Confidential Information separately and apart from any transcript page(s) not containing such Confidential Information. The parties shall treat every deposition transcript as if designated "CONFIDENTIAL" for thirty (30) calendar days following receipt of the transcript unless all parties agree prior to the expiration of that period that such transcript will not be designated as "CONFIDENTIAL."

9. Confidential Information shall be disclosed by the Receiving Party only to the following persons:

a. counsel of record for the Receiving Party, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel who are working on this action under the direction of such counsel and to whom it is necessary that the materials be disclosed for purposes of this action;

- b. in-house counsel employed by the Receiving Party with responsibility for this action, and the paralegals and stenographic and clerical employees of such counsel;
- c. to a named party in this action or their insurer, provided that the party or insurer complies with the terms and requirements set forth in this Protective Order;
- d. any outside consultant or expert who is assisting a party in this action, to whom it is necessary to disclose Confidential Information for the purposes of assisting in, or consulting with respect to, the preparation of this action, regardless of whether the consultant or expert is formally retained by the party itself or by the party's outside counsel; provided, however, that no Confidential Information shall be disclosed to any person who is, at the time of disclosure, an officer, director or employee of any other pharmaceutical manufacturer, developer, marketer, or seller, except as set forth in paragraph 11;
- e. any consultant or expert who is under contract to or employed by a party in this action for services independent of this litigation and who is assisting a party in this action, to whom it is necessary to disclose Confidential Information for purpose of assisting in, or consulting with respect to, the preparation of this action, regardless of whether the consultant or expert is formally retained by the party itself or by the party's outside counsel; provided, however, that no Confidential Information shall be disclosed to any person who is, at the time of disclosure, an officer, director or employee of any other pharmaceutical manufacturer, developer, marketer, or seller, except as set forth in Paragraph 11;
- f. the Court and any members of its staff to whom it is necessary to disclose Confidential Information for the purpose of assisting the Court in this action and under

the procedures set forth in Paragraph 14, *infra*;

g. stenographic employees and court reporters recording or transcribing testimony in this action; and

h. deposition witnesses in this action, provided that disclosing party complies with Paragraph 25 of this Protective Order.

10. Persons having knowledge of Confidential Information by virtue of their participation in the conduct of this action shall use that Confidential Information only in connection with the prosecution, defense, or appeal of this action, and shall neither use such Confidential Information for any other purpose nor disclose such Confidential Information to any person who is not listed in Paragraph 9 of this Protective Order.

11. Before disclosing Confidential Information to any person identified in Paragraph 9 (other than the Court or its staff) who is, at the time of disclosure, a director, officer, or employee of any other pharmaceutical manufacturer, developer, marketer, or seller, the party wishing to make such disclosures shall give at least ten (10) days advance notice in writing to the counsel who designated such information as confidential, stating the names and addresses of the person(s) to whom the disclosure will be made and precisely what confidential information is proposed to be disclosed. If, within the ten-day notice period, a motion is filed objecting to the proposed disclosure, the designated document or item shall not be disclosed unless and until the Court denies the motion objecting to the proposed disclosure, and shall not be disclosed except as permitted by the Court. For good cause shown, the notice of any such motion may be shortened by the Court upon the request of any party on an *ex parte* basis, but in no event shall the ten-day notice period be reduced.

12. Disclosure of Confidential Information beyond the terms of this Protective Order

may be made only if the Supplying Party designating the material as “CONFIDENTIAL” consents in writing to such disclosure, or if the Court, after reasonable written notice to all affected parties, orders such disclosure.

13. Any party that is served with a subpoena or other notice, in this action or any other action, compelling the production of any Confidential Information produced by another party must give written notice of such subpoena or other notice to lead counsel for the original Supplying Party in this action within seven (7) calendar days. Upon receiving such notice, the original Supplying Party shall bear the burden of opposing, if it deems appropriate, the subpoena on grounds of confidentiality.

14. Should documents or transcripts designated as Confidential be used as exhibits to any court filing or in any court proceeding in this action, the filing Party must comply with the procedures in section T (1) of the Court’s Electronic Case Filing Administrative Policies and Procedures Manual (Rev. Jan. 25, 2010). (“ECF Manual”) Each time a party seeks to file under seal confidential documents, things, and/or information, said party shall accompany the request with a motion to seal and a supporting memorandum of law specifying

- a. the exact documents, things, and/or information, or portions thereof, for which the filing under seal is requested;
- b. where it is necessary for the court to determine the source of the public’s right to access before a request to seal may be evaluated, whether any such request to seal seeks to overcome the common law or the First Amendment presumption to access;
- c. the specific qualities of the material at issue which justify sealing such material, taking into account the balance of competing interests in access;

- d. the reasons why alternatives to sealing are inadequate; and,
- e. whether there is consent to the motion.

Finally, in addition to the motion and supporting memorandum, said party must set out such findings in a proposed order to seal for the court. However, in the event that a party seeking to file Confidential Information is not the party who designated the material as Confidential Information, then the Filing Party and the Supplying Party shall follow the procedures set forth in section T (1)(a)(6) of the Court's ECF Manual. When a party seeks to file confidential documents, things, and/or information, including confidential portions of any transcript, a party shall submit such materials to the court in a sealed envelope or other appropriately sealed container, which covering shall be endorsed with the title of this action and a statement substantially in the following form: "Filed Under Seal Pursuant to Protective Order."

15. Counsel shall take all reasonable and necessary steps to assure the security of any Confidential Information and will limit access to Confidential Information to those persons listed in Paragraph 9 of this Protective Order. Further, any party may request that the Court close the court to the public when Confidential Information will be discussed.

16. Any Supplying Party may redesignate any inadvertently produced information as Confidential Information or withdraw a Confidential Information designation from any material that it has produced ("Redesignated Material"). Such redesignation shall be accomplished by notifying counsel for each party in writing of such redesignation. Upon receipt of any such redesignation, counsel shall (i) not make any further disclosure or communication of such Redesignated Material except as provided for in this Protective Order; (ii) take reasonable steps to notify any persons known to have possession of any Redesignated Material of such redesignation under this Protective Order; and (iii) take reasonable steps to procure all copies of

such Redesignated Material from any persons known to have possession of any Redesignated Material who are not entitled to receipt under Paragraph 9. Notwithstanding the foregoing, it is up to the Supplying Party to initiate action, which the Receiving Party will not oppose, to retrieve from the Court or place under seal Redesignated Material that the Receiving Party submitted to the Court prior to the redesignation.

17. Prior to the disclosure of any Confidential Information to any person identified in Paragraph 9 (other than the Court and its staff), such person shall be provided with a copy of this Protective Order, which he or she shall read. Upon reading this Protective Order, such person shall sign a Certification, in the form annexed hereto as Exhibit "A", acknowledging that he or she has read this Protective Order and shall abide by its terms. A file of all executed Certifications shall be maintained by outside counsel for the party obtaining them and shall be made available, upon request, for inspection by the Court in camera. Persons who come in contact with Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Certifications.

18. Any party may request at any time permission to disclose Confidential Information to a person other than those permitted under Paragraph 9, or to use such information in a manner otherwise precluded by this Protective Order, by serving a written request upon the Supplying Party's counsel. Any such request shall state the material the party wishes to disclose, to whom it wishes to make disclosure, and the reason and purpose therefore. The Supplying Party or its counsel shall thereafter respond to the request in writing (by hand delivery or facsimile transmission) within ten (10) business days of its receipt of such request, and if consent is withheld, it shall state the reasons why consent is being withheld. A failure to respond within such ten-day period shall constitute a denial of the request. If, where the consent is withheld, the

Requesting Party and the Supplying Party are subsequently unable to agree on the terms and conditions of disclosure, disclosure may only be made in accordance with the Supplying Party's designation of the material unless and until differing treatment is directed pursuant to an order of the Court.

19. Any party may object to the propriety of the designation (or redesignation) of specific material as "CONFIDENTIAL" by serving a written objection upon the Supplying Party's counsel. The Supplying Party or its counsel shall thereafter, within ten (10) calendar days, respond (by hand delivery or facsimile transmission) to such objection in writing by either: (i) agreeing to remove the designation; or (ii) stating the reasons for such designation. If the Objecting Party and the Supplying Party are subsequently unable to agree upon the terms and conditions of disclosure for the material(s) in issue, the Objecting Party shall be free to move the Court for an order removing or modifying the disputed designation. On such a motion the Supplying Party shall have the burden of proving that the material is Confidential. The material(s) in issue shall continue to be treated in the manner as designated by the Supplying Party until the Court orders otherwise.

20. Notwithstanding any other provisions hereof, nothing in the foregoing shall restrict any party's counsel from rendering advice to its clients with respect to this action and, in the course thereof, relying upon Confidential Information, provided that in rendering such advice, counsel shall not disclose any other party's Confidential Information other than in a manner provided for in this Protective Order.

21. Nothing in this Protective Order shall be deemed a waiver of any type of privilege applicable to any type of information in this or any other action or proceeding. Nothing in this Protective Order shall be construed to affect the evidentiary admissibility of any Confidential

Information or limit the use of any Confidential Information at trial (subject to rulings on admissibility).

22. Inadvertent production of documents subject to work-product doctrine, the attorney-client privilege or other legal privilege protecting information from discovery shall not constitute a waiver of the immunity or privilege, provided that the Supplying Party shall promptly notify the Receiving Party in writing when it becomes aware of such inadvertent production. Such inadvertently produced documents and all copies thereof, as well as all notes or other work product reflecting the contents of such materials, shall be returned to the Supplying Party or destroyed, upon request, and such returned or destroyed material shall be deleted from any litigation-support or other database. No use shall be made of such documents during deposition or at trial, nor shall they be shown to anyone who was not given access to them prior to the request to return or destroy them, unless otherwise permitted by the Court.

23. Upon the termination of this action, whether by Court order, judgment, settlement, or otherwise, including the termination of any appeals, at the written request and option of the Supplying Party, all Confidential Information and any and all copies, summaries, notes, compilations (electronic or otherwise), and memoranda related thereto, (including all Confidential Information and materials relating thereto in the possession of a party's expert witnesses and consultants) shall be returned within thirty (30) calendar days to the Supplying Party, provided, however, that counsel may retain their attorney work product and all court-filed documents even though they may contain Confidential Information, but such retained work product and court-filed documents shall remain subject to the terms of this Protective Order. At the written request of the Supplying Party, any person or entity having custody or control of recordings, notes, memoranda, summaries, or other written materials, and all copies thereof,

relating to or containing Confidential Information shall deliver to the Supplying Party an affidavit certifying that reasonable efforts have been made to assure that all such Confidential Information and any copies thereof, any and all records, notes, memoranda, summaries, or other written material regarding the Confidential Information (except for attorney work product and court-filed documents as stated above) have been delivered to the Supplying Party in accordance with the terms of this Protective Order. This Protective Order, and the obligation to keep Confidential Information confidential, shall survive the final termination of this action.

24. If Confidential Information is disclosed to any person other than in the manner authorized by this Protective Order, the party responsible for the disclosure shall immediately upon learning of such disclosure inform the Supplying Party of all pertinent facts relating to such disclosure and shall make all reasonable efforts to remedy the unauthorized disclosure, and if unsuccessful, immediately meet and confer with the Supplying Party to agree upon further appropriate steps to remedy the unauthorized disclosure.

25. Counsel for a party may show documents marked "CONFIDENTIAL" to a non-party deponent during a deposition upon providing five (5) business days' prior notice to the Supplying Party. If, within the five-business-day notice period, a motion is filed objecting to the proposed disclosure, the designated document or item shall not be disclosed unless and until the Court denies the motion objecting to the proposed disclosure, and shall not be disclosed except as permitted by the Court. Where Confidential Information is shown to a non-party deponent during a deposition, such document(s) or information will remain Confidential and the deposition transcript will be designated as Confidential. Counsel for a party may show documents marked "CONFIDENTIAL" to a non-party deponent without the notice specified above if counsel reasonably believes that the non-party deponent has previously seen the

document or is aware of the information contained therein or if the deponent is an employee of the party producing the document. Confidential Information shall not lose its Confidential or restricted status through such use, and counsel shall exercise their best efforts and take all steps reasonably required to protect its Confidentiality and restricted status during such use.

26. Nothing contained in this Protective Order shall preclude any party from using its own Confidential Information in any manner it sees fit, without prior consent of any party or the Court.

27. This Protective Order does not address the offering of Confidential Information in evidence at trial or any court hearing, but nothing contained in this Protective Order shall preclude any party from moving the Court at an appropriate time for an order that the evidence be reviewed in camera or under other conditions to prevent unnecessary disclosure.

28. In accordance with the provisions of 21 C.F.R. § 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients shall be treated as Confidential and shall not be disclosed.

29. Any and all medical records (including without limitation, mental health records) obtained in this case shall be treated as Confidential, regardless of whether such records are designated as Confidential Information. Such medical records shall be used only in connection with the prosecution, defense, or appeal of this action, and such medical records shall not be used for any other purpose or disclosed to any person who is not listed in Paragraph 9 of this Protective Order. This shall apply to any and all medical records produced by a party, medical records obtained pursuant to an Authorization for Release of Medical Records executed by a party to this litigation, medical records obtained pursuant to a subpoena or other legal process, and/or medical records obtained or produced by any other means. For purposes of this Order, the

term “medical record” means a writing in the possession of a health care provider that relates to the professional services that the health care provider rendered to the respective plaintiff.

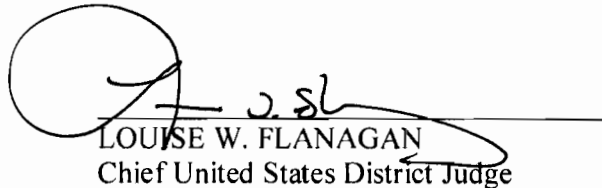
30. It is expressly understood by and between the parties that in producing Confidential Information in this litigation, the parties shall be relying upon the terms and conditions of this Protective Order.

31. Following the entry of any court order affecting Confidential Information, any party may request that the Court’s order be stayed so as to allow that party to take an appropriate writ to the Court of Appeals. Any party seeking the stay request shall have the burden of proving that there is good cause to grant the stay.

32. By written agreement of the parties, or upon motion and order of the Court, the terms of this Protective Order may be amended or modified. This Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive any final judgment or settlement in this action.

33. Failure to comply with this Protective Order shall be a basis for court-ordered sanctions or other appropriate relief.

Dated: March 23, 2010


LOUISE W. FLANAGAN
Chief United States District Judge

APPROVED AS TO FORM AND CONTENT:

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**EXHIBIT "A" TO STIPULATED PROTECTIVE ORDER REGARDING
THE CONFIDENTIALITY OF DOCUMENTS AND MATERIALS**

The undersigned hereby acknowledges that, having read the Stipulated Protective Order regarding the Confidentiality of Documents and Materials (the "Protective Order") filed in the case of *Tracey Cobb v. Abbott Laboratories, Incorporated; Abbott Laboratories, Inc. doing business as Abbott Sales, Marketing & Distribution Co.; and, Abbott Laboratories*, the undersigned understands the terms thereof and agrees to be bound thereby. The undersigned further agrees to submit to the jurisdiction of the Court for purposes of enforcement of the provisions of the Protective Order and understands that the Court may impose sanctions for any violation of the Protective Order.

The undersigned is not currently an officer, director, or employee of any other pharmaceutical manufacturer, developer, marketer, or seller.

Name (type or print)

Date

Signature